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OBLON SPIVAK MCCLELLAND MAIER & NEUSTADT PC
FOURTH FLOOR
1755 JEFFERSON DAVIS HIGHWAY
ARLINGTON, VA 22202

EXAMINER	
ROBINSON, BINTA M	
ART UNIT	**PAPER NUMBER**
1625	9

DATE MAILED: 12/13/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/865,420	Applicant(s) OHKUBO ET AL.	
	Examiner Binta M. Robinson	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *21* is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. *08/495,572* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

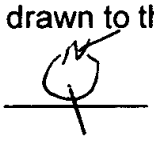
DETAILED ACTION

The examiner notes the applicant's election of the compound of claim 21 at paper no. 7. The election of species will be used as a reference point for the examiner to create a natural genus based on a liberal interpretation of the doctrine of legal and chemical equivalence and restriction will be required under 35 U. S. C. 121.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-21, drawn to the compound of the formula in claim 1 where R1 is saturated or unsaturated piperidine, substituted by X at the 4 position, where X is O, S, or NH, l is 0 or 1, A1 is lower alkyl optionally substituted with nonheterocyclic ring substituents, m is 0 or 1, the  moiety is saturated or unsaturated piperidine substituted at the Nitrogen with the Y moiety and at the 3 position with A2 and optionally substituted with nonheterorings substituents, A2 is lower alkylene optionally substituted with nonheteroring substituents, Z is –(C(O)(R3)-, where R3 is H, or AK, A3 is lower alkyl optionally substituted with nonheteroring substituents , R2 is carboxyl or protected carboxyl, the process of producing the compound of claim 1, and a pharmaceutical composition of claim 1, classified in class 546, subclass 188.

II. Claims 1-21, drawn to the compound of the formula in claim 1 where R1, A2, Z, X, the  moiety, and A3 are all other substituents not

claimed in claim 1, the process of making the compound of claim 1, and a pharmaceutical composition, classified in various classes and subclasses. The inventions are distinct, each from the other because of the following reasons:

In the instant case the different inventions have achieved a separate status in the art, have separate fields that aren't coextensive, and are capable of supporting separate patents. Further, a prior art reference that would anticipate the claims under 35 USC 102(b) would not render obvious the same claim(s) under 35 U. S. C. 103 (a) with respect to another member. Searching the entire genus would be a burden on the USPTO in terms of time and expense.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

By virtue of applicant's election of species falling into group 1, group 1 will be examined. If applicant prosecutes group II in a divisional application, this group may be subject to further restriction.

The unelected portions of claims 1-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 1-20 are objected to as being drawn to an improper Markush group on the grounds of lack of a common nucleus. The improper Markush group objection finds antecedent basis in case law. Compare In re Swensen 156 USPQ 180; In re Ruzicka 66 USPQ 226; In re Winnek 73 USPQ 225; In re Harnish 206 USPQ 300, 305 (CCPA 1980).

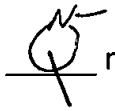
1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim s 1-20 in part are rejected under 35 U.S.C. 112, first paragraph, because the specification, is not enabling for R1 equal to all N-containing cycloalkyl groups which may have one or more suitable subituents, all ____ moieties, and the prevention of the diseases claimed in claim 17 as well as the treatment of the various unrelated diseases claimed in claim 17. Pharmaceutical drugs usually treat, not prevent disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement. The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to ***In re Wands***, 858 f.2d 731, 737, 8

USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in ***Ex parte*** Foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1)the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In the present case regarding factor 1, the breadth of the claimed invention encompasses R1 equal to a N-containing cycloalkyl, which may have one or more suitable substituents, and a  moiety, which is an N-containing heterocyclic group, which may have one or more suitable substituents. However, the examples in the specification do not encompass the entire scope of the Markush groups claimed. In regards to factor 2, the nature of the invention cannot be determined in light of the foregoing and without knowing the exact therapeutic compounds and/or generic core structures of those compounds/compositions and/or additional therapeutic agents that are comprised in the claimed pharmaceutical composition; only the compound of example 21 on page 47, line 30 of the specification, was tested to show the utility of the invention. The compound of example 21 is not representative of the entire scope of the

Markush group claimed in claim 1, especially concerning R1 or the N-containing heterocyclic group with regard to its platelet aggregation properties.

In terms of factor 3 and 5, the state of the art and the level of predictability in the art cannot be predicted with any certainty beyond what specific test compounds /compositions and/or additional therapeutic agents should be used and are likely to provide productive results beyond those therapeutic compounds/compositions and/or additional therapeutic agents taught in the specification. Only example 21 was tested for its affect on platelet aggregation.

In terms of factors 4 and 6, the inventor provides no guidance beyond the therapeutic compound/compositions and/or therapeutic agents as taught in the specification as previously mentioned. As a result one of ordinary skill in the art could not predict what other types of therapeutic compounds/compositions and/or additional therapeutic agents, other than those taught in the specification; and with regards to the 7^{th} and 8^{th} wands factor, while the existence of working examples are limited to the aforementioned compounds/compositions as taught in the specification (example 21), an indeterminate quantity of experimentation would be necessary to determine all potential therapeutic compounds/compositions' effects on platelet aggregation and actual diseases claimed in claim 17.

In terms of the 8^{th} Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not

seen where the instant claim is enabled by the instant application.

3. Claim 15 in part provide for the use of the compound, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 15 in part is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-20 in part are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 1, lines 4-5, and all other occurrences in claims 1-20, the phrase "which may have one or more suitable substituents" is indefinite. The term "maybe" is indefinite and should be replaced with "optionally". The phrase "one or more" is unbounded and has no upper limit. Additionally, it is not clear as to which substituents are being claimed.

B. Claim 16 in part is indefinite for being improper product use claims. Applicant is referred to Clinical Products v. Brenner -Commissioner of Patents) 149 USPQ 475 (District Court DC 66) Ex parte Dunki 153 USPQ 678 (Bd of Appeals 1967).

5. The elected species of claim 21 is allowable.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

Binta Robinson

December 12, 2001

Alan L. Rotman

ALAN L. ROTMAN
PRIMARY EXAMINER